〔一 般 論 文〕

タムスロシン塩酸塩口腔内崩壊錠 0.1 mg の製剤品質および服用性の臨床的評価

Clinical Evaluation of Formulation Quality and Ingestibility of Tamsulosin Hydrochloride Orally Disintegrating Tablets 0.1 mg

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Received February 26, 2016
Accepted March 24, 2016

Summary: We examined PTP (press through package) pushing out strength, hardness, friability and dissolution behavior to evaluate the formulation quality of a brand-name and four generic tamsulosin hydrochloride orally disintegrating (OD) tablets. The PTP pushing out strength was approximately 25 N for all formulations, and this data indicates that many users do not have much difficulty with pushing out. The hardness and friability were more than 0.02 kg/mg and less than 1 %, respectively, for all formulations, suggesting that all formulations could endure vibration and fall impact. However, the dissolution behaviors were different between formulations. Therefore, in the case of switching to other formulations, it is considered that careful observation of efficacy and side effects is required. Also, sensory testing, such as disintegration time in oral cavity, taste, and palatability, for healthy subjects was carried out to evaluate the ingestibility of tamsulosin hydrochloride OD tablets. The disintegration time in oral cavity was approximately 20 seconds for all formulations, showing that all formulations have a suitable disintegration time. For taste, most subjects did not taste bitterness in any of the formulations, and many subjects felt a rough and powdery consistency with several formulations. In addition, regarding palatability, most subjects described all formulations as easy to take. This study provides useful information for selecting the brand-name or generic tamsulosin hydrochloride OD tablets.

Key words: tamsulosin, orally disintegrating tablets, formulation quality, sensory testing, ingestibility

要旨：タムスロシン塩酸塩口腔内崩壊錠（OD 錠）の先発品 1 種と後発品 4 種の臨床使用における製剤品質を評価するため，PTP 押し出し強度，硬度および摩損度を測定するとともに，溶出試験を実施した．PTP 押し出し強度は，いずれの銘柄も 25 N 程度であり，押し出しにくさを感じるほどの値ではなかった．また，いずれの銘柄も硬度は 0.02 kg/mg 以上，摩損度は 1%以下であり，自動分包機での落下衝撃や通常の持ち運びには十分耐えうることが示された．一方，溶出挙動は銘柄により異なったため，銘柄変更の際には，薬効・副作用発現の観点から注意が必要と考えられる．また，服用性を評価するため，健常人に対する官能試験を実施した．口腔内での崩壊時間は，いずれの銘柄も約 20 秒であり，適切な崩壊時間を有していることが示された．味については，いずれの銘柄においても，大半の被験者が「苦み」を感じないと回答した．服用感については，「ざらつき」や「粉っぽさ」を感じやすい銘柄があった．嗜好性については，いずれの銘柄もおおむね 3 分の 2 以上の被験者が「服用してもよい」と回答した．本研究の結果は，

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